



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/687,568

10/15/2003

Lasse Wesseltoft Mogensen

8465/40

7139

757 7590 05/23/2008
BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610

EXAMINER

MACNEILL, ELIZABETH

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

05/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Allowable Subject Matter

1. Claims 40-43, 50-54, 67, and 68 are allowed.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 55, 57, 60, 66, 70, 71 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Miskinyar (US 4,894,054).

Miskinyar teaches an injector device with an infusion set having a housing (74) and a hollow cannula (22), a molded device housing (10), a cover (38), a plunger (18), a drive (70), a lock (56), and the device housing being manually deformable (button 33) to release the plunger. See Figs 1 and 2. As to claim 60, see cover 62 with hollow 60.

4. Claims 55-57, 60-64, 66, and 69-72 are rejected under 35 U.S.C. 102(e) as being anticipated by Safabash et al (US 6,293,925).

Safabash teaches an injector device with an infusion set having a housing (400) and a cannula (402) with tubing (412); a device housing (500), a cover (414), a plunger (504),

a spring drive (507), lock (552), and manually deformable housing (508, 510, 512) to release the plunger. See Figs 35-40g.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Safabash as applied to claims above, and further in view of Teeple, Jr (US 5,807,316).

Safabash does not teach indicia relating to the shelf life of the device on the cover. As to claim 59, see Figs 40a-40d. Teeple teaches that it is known in the art to encode the shelf life of a device in a bar code on the device (Col 18 line 25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the indicia of Teeple to avoid providing an expired device to the patient.

Response to Arguments

7. Applicant's arguments have been considered but are not persuasive. The button of Miskinyar is considered part of the housing because it covers the top of the device. As to claim 66, any part is removable. Applicant does not claim that the **infusion set is removable from the injector device while the cannula remains in the skin** as argued. As to Safabash, cover 414 clearly covers the entire needle, see Fig 40b, and is

suitable for sterilization. Again, the button is still considered part of the housing because it covers the top of the device. The rejections are maintained.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767